

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMITTAL
FORM**

(to be used for all correspondence after initial filing)

| | |
|------------------------|----------------|
| Application Number | 09/633,034 |
| Filing Date | August 4, 2000 |
| First Named Inventor | Tsang, et al. |
| Art Unit | 1642 |
| Examiner Name | L.R. Helms |
| Attorney Docket Number | 072771.0106 |

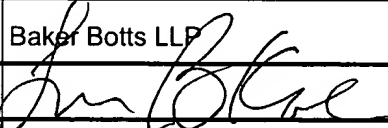
Number of Pages in This Submission

ENCLOSURES (Check all that apply)

- | | | |
|--|--|--|
| <input checked="" type="checkbox"/> Fee Transmittal Form <input checked="" type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): (1) Letter (2) Response to Notice of Non-Complaint Amendment (3) Supplemental Response (4) Second Declaration of Dr. J. Fasick |
|--|--|--|

Remarks

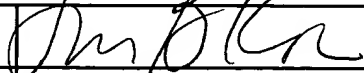
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

| | | | |
|--------------|---|--------------|--------|
| Firm Name | Baker Botts LLP | Customer No. | 21003 |
| Signature |  | | |
| Printed name | Lisa B. Kole | | |
| Date | 08/10/2005 | Reg. No. | 35,225 |

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature



Typed or printed name

Lisa B. Kole

Date

08/10/2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



A33081-R 072771.0106
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Tsang et al.

Serial No.: 09/633,034

Examiner: Helms, L.R.

Filed : August 4, 2000

Group Art Unit: 1642

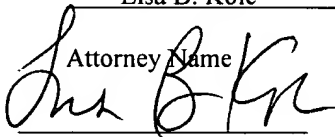
For : MONOCLONAL ANTIBODIES AGAINST HUMAN COLON CARCINOMA-
ASSOCIATED ANTIGENS AND USES THEREFOR

LETTER

I hereby certify that this paper is being deposited on August 10, 2005 with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450

Lisa B. Kole

35,225


Attorney Name

PTO Registration No.

August 10, 2005

Signature

Date of Signature

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice of Non-compliant Amendment dated June 30, 2005 ("the Notice"), Applicants submit herewith a Response To Notice. Also submitted herewith are a Supplemental Response, a Second Declaration of Dr. Jeffrey Fasick Under 37 C.F.R. §1.132, and an Information Disclosure Statement.

The Examiner is respectfully requested to make all these documents and the
remarks contained therein of record.

Respectfully submitted,
BAKER BOTTS L.L.P.

By: 

Lisa B. Kole
Patent Office Reg. No. 35,225
Attorney for Applicant

30 Rockefeller Plaza
New York, NY 10012-4498
(212)-408-2500

1. Chong, G., F. T. Lee, et al. (2005). "Phase I Trial of 131I-huA33 in Patients with Advanced Colorectal Carcinoma." *Clin Cancer Res* 11(13): 4818-26.
2. Koppe, M. J., R. P. Bleichrodt, et al. (2005). "Radioimmunotherapy and colorectal cancer." *Br J Surg* 92(3): 264-276.
3. Mallegol, J., G. van Niel, et al. (2005). "Phenotypic and functional characterization of intestinal epithelial exosomes." *Blood Cells Mol Dis* 35(1): 11-16.
4. Scott, A. M., F. T. Lee, et al. (2005). "A Phase I Trial of Humanized Monoclonal Antibody A33 in Patients with Colorectal Carcinoma: Biodistribution, Pharmacokinetics, and Quantitative Tumor Uptake." *Clin Cancer Res* 11(13): 4810-4817.
5. Deckert, P. M., W. G. Bornmann, et al. (2004). "Specific tumour localisation of a huA33 antibody--carboxypeptidase A conjugate and activation of methotrexate-phenylalanine." *Int J Oncol* 24(5): 1289-95.
6. Joosten, C. E., L. S. Cohen, et al. (2004). "Glycosylation profiles of the human colorectal cancer A33 antigen naturally expressed in the human colorectal cancer cell line SW1222 and expressed as recombinant protein in different insect cell lines." *Biotechnol Prog* 20(4): 1273-9.
7. Deckert, P. M., C. Renner, et al. (2003). "A33scFv-cytosine deaminase: a recombinant protein construct for antibody-directed enzyme-prodrug therapy." *Br J Cancer* 88(6): 937-9.
8. Mao, Z., S. Song, et al. (2003). "Transcriptional regulation of A33 antigen expression by gut-enriched Kruppel like factor." *Oncogene* 22(28): 4434-43.
9. Welt et al., 2003, Phase I Study of Anticancer Humanized Antibody A331. *Clinical Cancer Res.* 9(4):1338-1346.
10. Welt, S., G. Ritter, et al. (2003). "Preliminary report of a phase I study of combination chemotherapy and humanized A33 antibody immunotherapy in patients with advanced colorectal cancer." *Clin Cancer Res* 9(4): 1347-53.
11. United States Patent No. 6,346,249, issued February 12, 2002, by Barbas III et al. for Methods for reducing the effects of cancers that express A33 antigen using A33 antigen specific immunoglobulin products, filed April 4, 2000.
12. United States Patent No. 6,342,587, issued January 29, 2002 by Barbas III et al., A33 antigen specific immunoglobulin products and uses thereof, filed October 22, 1999.
13. Johnstone, C. N., S. J. White, et al. (2002). "Analysis of the regulation of the A33 antigen gene reveals intestine-specific mechanisms of gene expression." *J Biol Chem* 277(37): 34531-9.

14. Orlova, A., J. Hoglund, et al. (2002). "Comparative biodistribution of the radiohalogenated (Br, I and At) antibody A33. Implications for in vivo dosimetry." *Cancer Biother Radiopharm* 17(4): 385-96.
15. van Niel, G. and M. Heyman (2002). "The epithelial cell cytoskeleton and intracellular trafficking. II. Intestinal epithelial cell exosomes: perspectives on their structure and function." *Am J Physiol Gastrointest Liver Physiol* 283(2): G251-5.
16. Barendswaard, E. C., J. L. Humm, et al. (2001). "Relative therapeutic efficacy of (125)I- and (131)I-labeled monoclonal antibody A33 in a human colon cancer xenograft." *J Nucl Med* 42(8): 1251-6.
17. Lee, F. T., A. Rigopoulos, et al. (2001). "Specific localization, gamma camera imaging, and intracellular trafficking of radiolabelled chimeric anti-G(D3) ganglioside monoclonal antibody KM871 in SK-MEL-28 melanoma xenografts." *Cancer Res* 61(11): 4474-82.
18. Ritter, G., L. S. Cohen, et al. (2001). "Serological analysis of human anti-human antibody responses in colon cancer patients treated with repeated doses of humanized monoclonal antibody A33." *Cancer Res* 61(18): 6851-9.
19. van Niel, G., G. Raposo, et al. (2001). "Intestinal epithelial cells secrete exosome-like vesicles." *Gastroenterology* 121(2): 337-49.
20. Abud, H. E., C. N. Johnstone, et al. (2000). "The murine A33 antigen is expressed at two distinct sites during development, the ICM of the blastocyst and the intestinal epithelium." *Mech Dev* 98(1-2): 111-4.
21. Deckert, P. M., A. Jungbluth, et al. (2000). "Pharmacokinetics and microdistribution of polyethylene glycol-modified humanized A33 antibody targeting colon cancer xenografts." *Int J Cancer* 87(3): 382-90.
22. Johnstone, C. N., N. C. Tebbutt, et al. (2000). "Characterization of mouse A33 antigen, a definitive marker for basolateral surfaces of intestinal epithelial cells." *Am J Physiol Gastrointest Liver Physiol* 279(3): G500-10.
23. Rader, C., G. Ritter, et al. (2000). "The rabbit antibody repertoire as a novel source for the generation of therapeutic human antibodies." *J Biol Chem* 275(18): 13668-76.
24. Ruan, S., J. A. O'Donoghue, et al. (2000). "Optimizing the sequence of combination therapy with radiolabeled antibodies and fractionated external beam." *J Nucl Med* 41(11): 1905-12.
25. Sakamoto, J., H. Kojima, et al. (2000). "Organ-specific expression of the intestinal epithelium-related antigen A33, a cell surface target for antibody-based imaging and treatment in gastrointestinal cancer." *Cancer Chemother Pharmacol* 46 Suppl: S27-32.

26. Barendswaard, E. C., J. A. O'Donoghue, et al. (1999). "¹³¹I radioimmunotherapy and fractionated external beam radiotherapy: comparative effectiveness in a human tumor xenograft." *J Nucl Med* 40(10): 1764-8.
27. Miyazono, Y., Y. Kamogawa, et al. (1999). "Effect of B7.1-transfected human colon cancer cells on the induction of autologous tumour-specific cytotoxic T cells." *J Gastroenterol Hepatol* 14(10): 997-1003.
28. United States Patent No. 5,958,412, issued September 28, 1999 by Welt et al.; for Methods of treating colon cancer utilizing tumor-specific antibodies, filed June 4, 1997.
29. Barendswaard, E. C., A. M. Scott, et al. (1998). "Rapid and specific targeting of monoclonal antibody A33 to a colon cancer xenograft in nude mice." *Int J Oncol* 12(1): 45-53.
30. Burgess, A. W. (1998). "Growth control mechanisms in normal and transformed intestinal cells." *Philos Trans R Soc Lond B Biol Sci* 353(1370): 903-9.
31. Moritz, R. L., G. Ritter, et al. (1998). "Micro-sequencing strategies for the human A33 antigen, a novel surface glycoprotein of human gastrointestinal epithelium." *J Chromatogr A* 798(1-2): 91-101.
32. Tio, T. L. (1998). "Diagnosis and staging of esophageal carcinoma by endoscopic ultrasonography." *Endoscopy* 30 Suppl 1: A33-40.
33. United States Patent No. 5,712,369, January 27, 1998 by Welt et al. for Isolated protein which binds to A33 antibody, and peptides corresponding to portions of the protein, filed February 2, 1996.
34. Catimel, B., M. Nerrie, et al. (1997). "Kinetic analysis of the interaction between the monoclonal antibody A33 and its colonic epithelial antigen by the use of an optical biosensor. A comparison of immobilisation strategies." *J Chromatogr A* 776(1): 15-30.
35. Heath, J. K., S. J. White, et al. (1997). "The human A33 antigen is a transmembrane glycoprotein and a novel member of the immunoglobulin superfamily." *Proc Natl Acad Sci U S A* 94(2): 469-74.
36. Ji, H., R. L. Moritz, et al. (1997). "Electrophoretic analysis of the novel antigen for the gastrointestinal-specific monoclonal antibody, A33." *Electrophoresis* 18(3-4): 614-21.
37. Ritter, G., L. S. Cohen, et al. (1997). "Characterization of posttranslational modifications of human A33 antigen, a novel palmitoylated surface glycoprotein of human gastrointestinal epithelium." *Biochem Biophys Res Commun* 236(3): 682-6.
38. Tschmelitsch, J., E. Barendswaard, et al. (1997). "Enhanced antitumor activity of combination radioimmunotherapy (¹³¹I-labeled monoclonal antibody A33) with chemotherapy (fluorouracil)." *Cancer Res* 57(11): 2181-6.

39. United States Patent No. 5,643,550, issued July 1, 1997 by Welt et al.; for Method of treating colorectal carcinoma lesion and composition for use therein, filed September 27, 1994.
40. No Author listed. (1996). "MoAb A33 shows promise in targeting colon cancer for radioimmunotherapy." *Oncology (Huntingt)* 10(4): 553.
41. Antoniow, P., A. P. Farnsworth, et al. (1996). "Radioimmunotherapy of colorectal carcinoma xenografts in nude mice with yttrium-90 A33 IgG and Tri-Fab (TFM)." *Br J Cancer* 74(4): 513-24.
42. Daghighian, F., E. Barendswaard, et al. (1996). "Enhancement of radiation dose to the nucleus by vesicular internalization of iodine-125-labeled A33 monoclonal antibody." *J Nucl Med* 37(6): 1052-7.
43. Welt, S., A. M. Scott, et al. (1996). "Phase I/II study of iodine 125-labeled monoclonal antibody A33 in patients with advanced colon cancer." *J Clin Oncol* 14(6): 1787-97.
44. King, D. J., P. Antoniow, et al. (1995). "Preparation and preclinical evaluation of humanised A33 immunoconjugates for radioimmunotherapy." *Br J Cancer* 72(6): 1364-72.
45. Scott, A. M., E. Rosa, et al. (1995). "In vivo imaging and specific targeting of P-glycoprotein expression in multidrug resistant nude mice xenografts with [125I]MRK-16 monoclonal antibody." *Nucl Med Biol* 22(4): 497-504.
46. Welt et al., 1994, Phase I/II Study of Iodine 131-Labeled Monoclonal Antibody A33 in Patients With Advanced Colon Cancer. *J. Clin. Oncol.* 12:1561-71
47. United States Patent No. 5,160,723, issued November 3, 1991 by Welt et al., for Method of imaging colorectal carcinoma lesion and composition for use therein, filed March 18, 1991.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that the listed documents are material or constitute “prior art.” If the Examiner applies the document(s) as prior art against any claim in the application and applicants determine that the cited document(s) do not constitute “prior art” under United States law, applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the document(s).

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed document(s), should the document(s) be applied against the claims of the present application.

Applicants believe that no fee in addition to the enclosed fee of \$ 180.00 under 37 C.F.R § 1.17(p) is due in connection with the filing of this Information Disclosure Statement. However, should any fee be required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit any overpayments made, to Deposit Account 02-4377. A duplicate copy of this paper is enclosed.

Respectfully submitted,
BAKER BOTTS L.L.P.

By: 

Lisa B. Kole
Patent Office Reg. No. 35,225
Attorney for Applicant

30 Rockefeller Plaza
New York, NY 10012-4498
(212)-408-2500

Enclosure

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Tsang et al.

Serial No.: 09/633,034

Examiner: Helms, L.R.

Filed : August 4, 2000

Group Art Unit: 1642

For : MONOCLONAL ANTIBODIES AGAINST HUMAN COLON CARCINOMA-
ASSOCIATED ANTIGENS AND USES THEREFOR

RESPONSE TO NOTICE

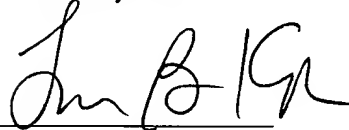
I hereby certify that this paper is being deposited on August 10, 2005 with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450

Lisa B. Kole

35,225

Attorney Name

PTO Registration No.



August 10, 2005

Signature

Date of Signature

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

In response to the Notice of Non-compliant Amendment dated June 30, 2005
("the Notice"), please consider the following remarks.

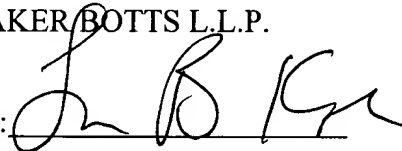
In the Notice, the Response submitted June 17, 2005 is said to be non-compliant
because "a complete listing of all of the claims is not present."

In response, Applicants respectfully bring to the attention of the Legal Instruments Examiner that this is a reissue application, so that 37 C.F.R. §1.121 does not apply. This was confirmed by the undersigned in a telephone conference with Examiner now Supervisor Larry Helms.

Therefore, it is respectfully requested that the objection to the submitted Response as non-compliant is withdrawn.

Because Applicants believe that the Notice was issued in error, it is believed that no extension of time for submission of this paper is required. If, however, an extension of time is deemed necessary, then this paper is to be considered a Petition to Extend Time for a period of one month, up to and including August 30, 2005, and the Commissioner is authorized to charge the required fee for a small entity to Deposit Account No. 02-4377.

Respectfully submitted,
BAKER BOTTS L.L.P.

By: 

Lisa B. Kole
Patent Office Reg. No. 35,225
Attorney for Applicant

30 Rockefeller Plaza
New York, NY 10012-4498
(212)-408-2500

Enclosure